

### REMARKS

On December 5, 2003, Applicant filed a petition to convert this Application into a Statutory Invention Registration (SIR). This Application contains the sequences of 325,720 SNP nucleic acids, all of which Applicant desires to dedicate to the public domain through a Statutory Invention Registration. Applicant's goal is to allow scientists to freely work on these sequences and possibly identify new diseases and/or correlate the sequences with existing disease states. By converting this Application into an SIR, Applicant wishes use the SIR defensively as a prior art document to ensure that no one entity can patent a sequence disclosed in this Application, thereby removing that sequence from the public domain and preventing the work of scientists on that sequence.

Applicant notes that because the Examiner found Applicant's argument in its Response to Restriction Requirement made Dec. 5, 2003 unpersuasive, the Restriction Requirement has been made final. Applicant is enclosing herewith a Petition From Restriction Requirement under 37 C.F.R. §1.144.

Claim 1 is pending.

Please reconsider the Application in light of the following remarks.

#### **I. The Claims Meet the Requirements of 35 U.S.C. § 101.**

Claim 1 was rejected under 35 U.S.C. §101 because the claimed invention allegedly "lacks patentable utility due to its not being supported buy a specific, substantial, and credible utility or, in the alternative, a well-established utility." (Office Action, p. 4).

Specifically, the Office Action has alleged that although the specification "asserts that the claimed SNP nucleic acids are useful in classifying people according to their genetic variation and in linking genetic [sic] information with human diseases" (Office Action, pp. 4-5), this "is not deemed as a specific utility because it is generic to any sequence variations and no specific diseases or conditions are specifically provided in the specification that could be linked with the

claimed SNP nucleic acid. Further, this utility is not considered substantial because further research is needed to determine what specific disease can the claimed SNP nucleic acid be used for linkage analysis.” (Office action, p. 5)

Applicants respectfully traverse these grounds for rejection.

As an initial matter, because Applicant is petitioning against the final Restriction Requirement, Applicant is addressing this ground for rejection with regard to claim 1 (as currently pending) as being drawn to a SNP probe consisting of an oligonucleotide that is complementary to a SNP nucleic acid selected from the SNP nucleic acids shown in SEQ ID NOs: 1-325,720 (*i.e.*, without being limited only to SEQ ID NO: 1).

Applicant respectfully notes that the Application provides ample evidence of specific, substantial, and credible and/or well-established utility for the claimed invention. For example, at page 16, line 21 through page 17, line 12, the Application describes using a SNP probe to determine if an individual is the source of a biological sample. Such a determination is useful, for example, in forensic analysis of blood or semen samples, or in paternity analysis. Applicant respectfully avers that not only is identification of a person based on their genetic sequences a specific, substantial, and credible utility, it is also a well-known utility, and is routinely done by forensic and medical laboratories throughout the world. 35 U.S.C. §101 requires nothing more for an Application to disclose a patentable utility.

Thus, Applicant avers that its invention, as presently claimed (*i.e.*, covering SEQ ID NOs: 1-325,720) meets the utility requirements of 35 U.S.C. §101. Based on the above remarks, Applicants respectfully request that this ground for rejection under 35 U.S.C. §101 be reconsidered and withdrawn.

### **III. The Claims Meet the Requirements of 35 U.S.C. § 112, First Paragraph.**

Claim 1 stands rejected under 35 U.S.C. §112, first paragraph, because “since the claimed

invention lacks patentability utility...one skilled in the art clearly would not know how to use the claimed invention.” (Office Action, p. 5).

Applicants traverse this ground of rejection.

Based on the arguments made above, Applicant respectfully avers that the claimed invention does indeed have patentable utility. As Applicants have overcome the 35 U.S.C. §101 ground for rejection, this 35 U.S.C. §112, first paragraph, rejection is rendered moot and should be withdrawn.

### CONCLUSION

Applicant filed this Application containing 325,720 sequences with the intention of dedicating these sequences to the public domain through a Statutory Invention Registration. The sole remaining requirement for converting this Application into an SIR appears to be the meeting of the requirements of 35 U.S.C. §112. Based on the above comments, Applicant respectfully submits that the Applicant now meets the requirements of 35 U.S.C. §112 and, as such, is in condition for grant as a Statutory Invention Registration. However, if the Examiner believes that any further discussion of this communication would be helpful, she is encouraged to contact the undersigned by telephone.

U.S. Serial No. 10/027,632  
Response under 37 CFR §1.111

No fees are believed to be due in connection with this communication. However, please apply any additional charges, or credit any overpayment, to our Deposit Account No. 08-0219.

Respectfully submitted,  
HALE AND DORR LLP

A handwritten signature in dark ink, appearing to read 'Nancy Wilker', is written over a horizontal line.

Nancy (Chiu) Wilker, Ph.D.  
Reg. No. 43,545  
Agent for Applicants

Date: May 25, 2004

60 State Street  
Boston, MA 02109  
(617) 526-6000  
(617) 526-5000 (fax)